



DOCKET NO.: C1039.70022US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.
Serial No.: 09/337,893
Confirmation No.: 9627
Filed: June 21, 1999
For: METHODS OF REDIRECTING AN IMMUNE RESPONSE
USING IMMUNOSTIMULATORY
OLIGONUCLEOTIDES
Examiner: Nita M. Minnifield
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 30 day of September, 2004.

Helen C. Lockhart, Ph.D., Reg. No. 39,248

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1037.70013US01	10/831,778	April 23, 2004	Bratzler et al.
*C1037.70039US01	10/816,220	April 1, 2004	McCluskie et al.
*C1037.70042US00	10/613,524	July 3, 2003	Krieg
*C1037.70048US00	10/644,052	August 19, 2003	Jurk et al.
*C1037.70049US00	10/643,141	August 18, 2003	Hutcherson et al.
*C1037.70052US00	10/668,050	September 22, 2003	Bratzler et al.
*C1039.70020US01	10/921,086	August 18, 2004	Krieg et al.
C1039.70035US00	09/669,187	September 25, 2000	Krieg et al.
*C1039.70035US01	10/884,866	July 2, 2004	Krieg et al.
*C1039.70035US02	10/888,803	July 9, 2004	Krieg et al.
C1039.70041US00	09/655,319	September 5, 2000	Krieg et al.
C1039.70042US00	09/630,319	July 31, 2000	Krieg et al.
C1039.70043US00	09/629,477	July 31, 2000	Krieg et al.
C1039.70044US00	09/672,126	September 27, 2000	Hartmann et al.
*C1039.70048US02	10/817,165	April 2, 2004	Krieg et al.
*C1039.70048US03	10/831,647	April 23, 2004	Krieg et al.
*C1039.70048US04	10/847,642	May 15, 2004	Krieg et al.
*C1039.70048US05	10/877,407	June 24, 2004	Krieg et al.
*C1039.70048US06	10/884,852	July 2, 2004	Krieg et al.
*C1039.70048US07	10/888,785	July 9, 2004	Krieg et al.
*C1039.70048US08	10/888,449	July 9, 2004	Krieg et al.
*C1039.70048US09	10/894,657	July 16, 2004	Krieg et al.

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<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1039.70048US10	10/894,862	July 16, 2004	Krieg et al.
*C1039.70048US11	10/928,762	August 26, 2004	Krieg et al.
C1039.70057US00	09/965,101	September 26, 2001	Davis et al.
*C1039.70057US01	10/838,659	May 3, 2004	Davis et al.
*C1039.70058US01	10/831,775	April 23, 2004	Davis et al.
C1039.70062US00	10/187,489	July 2, 2002	Krieg et al.
C1039.70070US00	10/382,822	March 6, 2003	Krieg et al.
C1039.70071US00	10/435,656	May 9, 2003	Krieg et al.
*C1039.70075US00	10/613,916	July 3, 2003	Krieg et al.
*C1039.70077US00	10/619,279	July 14, 2003	Krieg
*C1039.70079US00	10/627,413	July 25, 2003	Krieg et al.
*C1039.70083US03	10/788,199	February 26, 2004	Krieg et al.
*C1039.70083US08	10/847,650	May 15, 2004	Krieg et al.
*C1039.70083US09	10/888,885	July 9, 2004	Krieg et al.
*C1039.70083US10	10/888,089	July 9, 2004	Krieg et al.
*C1039.70084US00	10/649,584	August 25, 2003	Krieg et al.
*C1040.70006US01	10/888,886	July 9, 2004	McCluskie et al.
*C1040.70012US00	10/644,267	August 20, 2003	Davis et al.
*C1041.70002US01	10/877,369	June 25, 2004	Wagner et al.
*C1041.70002US02	10/876,965	June 25, 2004	Wagner et al.
*C1041.70002US03	10/876,892	June 25, 2004	Wagner et al.
C1041.70005US00	09/355,254	February 22, 2000	Wagner et al.
*C1041.70005US01	10/811,226	March 26, 2004	Wagner et al.
*C1041.70005US02	10/894,655	July 16, 2004	Wagner et al.
C1041.70010US00	09/786,436	March 2, 2001	Wagner et al.
*C1041.70016US01	10/884,372	July 2, 2004	Bauer et al.
*C1041.70024WO00	PCT/US04/12788	April 22, 2004	Vollmer et al.
*C1041.70036US01	10/872,196	June 18, 2004	Lipford et al.
*C1041.70040US00	10/666,844	September 19, 2003	Lipford et al.

*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

Comments Regarding Pending Interference No. 105,171

Applicants of the instant patent application are also named inventors on an issued patent US Patent No. 6,207,646 B1 which is currently involved in an Interference (Interference No. 105,171). The instant patent application derives priority from US 6,207,646 B1. In view of the priority Applicants have included on the attached 1449 a listing of the motions filed in the Interference. Copies are enclosed for the Examiner's review. If the Examiner would like any additional information on this subject, she is encouraged to contact Applicants' representative at the number listed below.

The Interference is with the following patent application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor</u>
09/265,191	03-10-1999	Carson et al.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

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By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

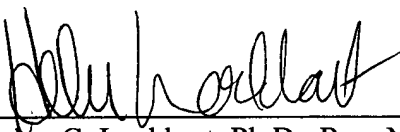
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

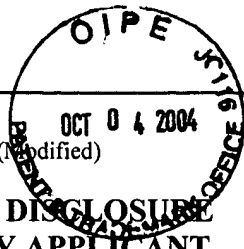
An early and favorable action is hereby requested.

Respectfully submitted,
Krieg et al., Applicant

By:


Helen C. Lockhart, Ph.D., Reg. No. 39,248
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: C1039,70022US00
Date: September 30, 2004
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FORM PTO-1449/A and B (Modified)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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APPLICATION NO.: 09/337,893

ATTY. DOCKET NO.: C1039.70022US00

FILING DATE: June 21, 1999

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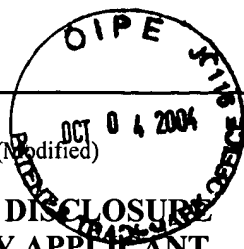
APPLICANT: Krieg et al.

GROUP ART UNIT: 1645

EXAMINER: Nita M. Minnifield

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A2	6,194,388	B1	Krieg et al.	02-27-2001
	A3	6,207,646	B1	Krieg et al.	03-27-2001
	A4	6,214,806	B1	Krieg et al.	04-10-2001
	A5	6,218,371	B1	Krieg et al.	04-17-2001
	A6	6,239,116	B1	Krieg et al.	05-29-2001
	A7	6,339,068	B1	Krieg et al.	01-15-2002
	A8	6,406,705	B1	Davis et al.	06-18-2002
	A9	6,429,199	B1	Krieg et al.	08-06-2002
	A10	2001-0044416	A1	McCluskie et al.	11-22-2001
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	A13	2002-0156033	A1	Bratzler et al.	10-24-2002
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	A21	2003-0055014	A1	Bratzler	03-20-2003
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	A23	2003-0100527	A1	Krieg et al.	05-29-2003
	A24	2003-0104523	A1	Bauer et al.	06-05-2003
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	A32	2004-0087534	A1	Krieg et al.	05-06-2004
	A33	2004-0087538	A1	Krieg et al.	05-06-2004
	A34	2004-0106568	A1	Krieg et al.	06-03-2004
	A35	2004-0131628	A1	Bratzler et al.	07-08-2004
	A36	2004-0132685	A1	Krieg et al.	07-08-2004
	A37	2004-0142469	A1	Krieg et al.	07-22-2004
	A38	2004-0143112	A1	Krieg et al.	07-22-2004



FORM PTO-1449/A and B (Modified)

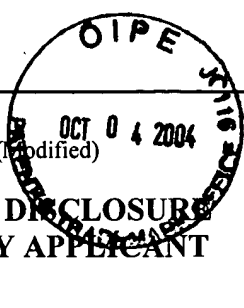
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

APPLICATION NO.: 09/337,893	ATTY. DOCKET NO.: C1039.70022US00
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APPLICANT: Krieg et al.	
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A57	6,534,062	B1	Raz et al.	03-18-2003
A58	6,562,798	B1	Schwartz	05-13-2003
A59	6,787,524	B2	Chang et al.	09-07-2004
A60	2002-0086839	A1	Raz et al.	07-04-2002
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A62	2003-0022852	A1	Van Nest et al.	01-30-2003
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A69	2003-0133988	A1	Fearon et al.	07-17-2003
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A76	2004-0064064	A1	Zhou et al.	04-01-2004
A78	2004-0092468	A1	Schwartz et al.	05-13-2004



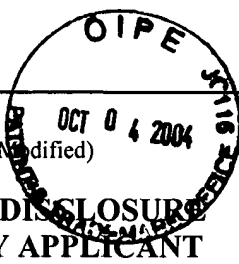
FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/337,893		ATTY. DOCKET NO.: C1039.70022US00		
				FILING DATE: June 21, 1999		CONFIRMATION NO.: 9627		
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				GROUP ART UNIT: 1645		EXAMINER: Nita M. Minnifield		
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FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B2	EP	0 302 758	A1	New England Medical Center Hospitals, Inc.	02-08-1989	
	B3	WO	96/40162	A1	East Carolina University	12-19-1996	
	B4	WO	98/16247	A1	The Regents of the University of California	04-23-1998	
	B5	WO	98/55495	A2	Dynavax Technologies Corporation	12-10-1998	
	B6	WO	99/11275	A2	The Regents of the University of California	03-11-1999	
	B7	WO	99/52549	A1	Smithkline Beecham Biologicals S.A.	10-29-1999	
	B8	WO	99/58118	A2	CPG Immunopharmaceuticals GMBH	11-18-1999	
	B9	WO	99/62923	A2	Dynavax Technologies Corporation	12-09-1999	
	B10	WO	00/16804	A1	Dynavax Technologies Corporation	03-30-2000	
	B11	WO	00/20039	A1	The Regents of the University of California	04-13-2000	
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	B16	WO	01/22972	A2	Coley Pharmaceuticals, GmbH	04-05-2001	
	B17	WO	02/052002	A2	Dynavax Technologies Corporation	07-04-2002	
	B18	WO	03/000232	A2	Dynavax Technologies Corporation	01-03-2003	
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	B20	WO	03/094963	A2	INEX Pharmaceuticals Corp.	11-20-2003	
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	B22	WO	2004/041183	A2	The Regents of the University of California	05-21-2004	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C10	[No Author Listed] Allergen Nomenclature, List of Allergens (as of March 12, 2004).	
	C11	[No Author Listed] Expert panel report 2: Guidelines for the diagnosis and management of asthma – Clinical practice guidelines. National Institutes of Health Publication. 1997 Jul; No. 97-4051:iii-79.	
	C12	ABED et al., Interferon-gamma regulation of B lymphocyte differentiation: activation of B cells is a prerequisite for IFN-gamma-mediated inhibition of B cell differentiation. Cell Immunol. 1994 Feb;153(2):356-66.	
	C13	AGRAWAL et al., Pharmacokinetics, biodistribution, and stability of oligodeoxynucleotide phosphorothioates in mice. Proc Natl Acad Sci U S A. 1991 Sep 1;88(17):7595-9.	
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FORM PTO-1449/A and B (Modified)

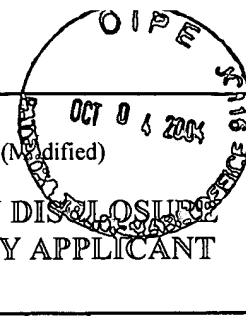
INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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APPLICATION NO.: 09/337,893
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 APPLICANT: Krieg et al.
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 CONFIRMATION NO.: 9627
 EXAMINER: Nita M. Minnifield

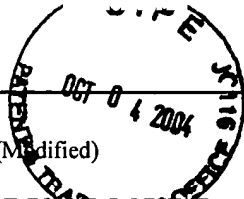
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C18	BRAZOLOT-MILLAN et al., "CpG DNA can induce strong Th1 humoral and cell-mediated immune responses against hepatitis B surface antigen in young mice", <i>Proceedings of the National Academy of Science USA</i> , 95: 15553-15558, 1998.		
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C20	BROIDE et al., Immunostimulatory DNA sequences inhibit IL-5, eosinophilic inflammation, and airway hyperresponsiveness in mice. <i>J Immunol</i> . 1998 Dec 15;161(12):7054-62.		
C21	BROIDE et al., Modulation of asthmatic response by immunostimulatory DNA sequences. <i>Springer Semin Immunopathol</i> . 2000;22(1-2):117-24. Review.		
C22	BRUNNER et al., "Enhanced dendritic cell maturation by TNF-alpha or cytidine-phosphate-guanosine DNA drives T cell activation in vitro and therapeutic anti-tumor immune responses in vivo", <i>Journal of Immunology</i> , 165: 6278-6286, 2000.		
C23	CARSON et al., Oligonucleotide adjuvants for T helper 1 (Th1)-specific vaccination. <i>J Exp Med</i> . 1997 Nov 17;186(10):1621-2.		
C24	CELLA et al., Plasmacytoid monocytes migrate to inflamed lymph nodes and produce large amounts of type I interferon. <i>Nat Med</i> . 1999 Aug;5(8):919-23.		
C25	CHACE et al., Bacterial DNA-induced NK cell IFN-gamma production is dependent on macrophage secretion of IL-12. <i>Clin Immunol Immunopathol</i> . 1997 Aug;84(2):185-93.		
C26	CHOI et al., "The level of protection against rotavirus shedding in mice following immunization with a chimeric VP6 protein is dependent on the route and the coadministered adjuvant", <i>Vaccine</i> , 20(13-14): 1733-40, 2002.		
C27	DAVIS et al., "Use of CpG DNA for enhancing specific immune responses", <i>Current Topics in Microbiology Immunology</i> , 247: 171-83, 2000.		
C28	DUNN et al., The three Es of cancer immunoediting. <i>Annu Rev Immunol</i> . 2004;22:329-60. Review.		
C29	DURHAM et al., Immunotherapy and allergic inflammation. <i>Clin Exp Allergy</i> . 1991 Jan;21 Suppl 1:206-10.		
C30	ELKINS et al., Bacterial DNA containing CpG motifs stimulates lymphocyte-dependent protection of mice against lethal infection with intracellular bacteria. <i>J Immunol</i> . 1999 Feb 15;162(4):2291-8.		
C31	FRANCOIS et al., Examination of the inhibitory and stimulatory effects of IFN-alpha, -beta, and -gamma on human B-cell proliferation induced by various B-cell mitogens. <i>Clin Immunol Immunopathol</i> . 1988 Sep;48(3):297-306.		
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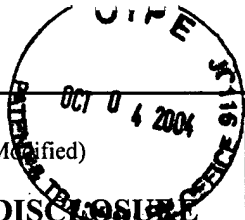
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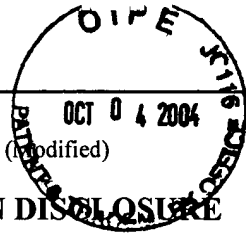
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C149	Patent Interference No. 105,171. Iowa Preliminary Motion 3 (for Judgment Based on Failure to Comply with 35 U.S.C. 135(b)) (Electronically filed, unsigned). June 7, 2004.		
C150	Patent Interference No. 105,171. Iowa Preliminary Motion 4 (For Judgment of No Interference in Fact) (Electronically filed, unsigned). June 7, 2004.		
C151	Patent Interference No. 105,171. Iowa Preliminary Motion 5 (For Judgment Based on Lack of Enablement) (Electronically filed, unsigned). June 7, 2004.		
C152	Patent Interference No. 105,171. Iowa Preliminary Motion 6 (For Judgment Based Lack of an Adequate Written Description) (Electronically filed, unsigned). June 7, 2004.		
C153	Patent Interference No. 105,171. Iowa Preliminary Motion 7 (Motion to Redefine the Interference to Designate Claims as Not Corresponding to the Count) (Electronically filed, unsigned). June 7, 2004.		
C154	Patent Interference No. 105,171. Iowa Preliminary Motion 8 (Contingent Motion to Redefine Count) (Electronically filed, unsigned). June 7, 2004.		
C155	Patent Interference No. 105,171. Iowa Preliminary Motion 9 (Motion for Benefit of Earlier Application) (Electronically filed, unsigned). June 7, 2004.		
C156	Patent Interference No. 105,171. Iowa Preliminary Motion 10 (Contingent Motion to Redefine the Interference By Adding A Continuation Application) (Electronically filed, unsigned). July 2, 2004.		
C157	Patent Interference No. 105,171. Regents of the University of California Preliminary Statement. June 7, 2004.		

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C161	Patent Interference No. 105,171. Regents of the University of California Preliminary Motion 4 (For Judgment Based on Obviousness). June 7, 2004.		
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C166	Amended Claims for Application Number 09/265,191, filed March 10, 1999.		

EXAMINE R	DATE CONSIDERED
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*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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